IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 08-948 (LDD)
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

APOTEX INC.'S AND APOTEX CORP.'S BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS

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Apotex Inc. and Apotex Corp. respectfully submit this brief in support of their motion to dismiss this action in its entirety.

I. INTRODUCTION.

The Court should dismiss all claims against Apotex Inc. for lack of personal jurisdiction under Rule 12(b)(2), FED. R. CIV. P., and permit this dispute to proceed in Illinois where jurisdiction is proper and related litigation involving the same patent and parties is already pending and proceeding. Because jurisdiction is lacking over the only party that matters (*i.e.*, Apotex Inc.), the Court should also dismiss the action against Apotex Corp. for lack of an indispensable party under Rule 19(b), FED. R. CIV. P.

Apotex Inc., a corporation organized, located, operating and existing *solely* in Canada, has submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") for a generic version of atorvastatin—a prescription drug marketed by Pfizer under the brand-name Lipitor®. Apotex Inc.'s ANDA contains a so-called "paragraph IV certification" stating that Pfizer's original patent-in-suit, U.S. Patent No. 5,273,995 ("the '995 patent"), is invalid and/or not infringed by Apotex Inc.'s proposed generic drug. As required by statute and regulation, Apotex Inc. provided notification of its Paragraph IV ANDA to Pfizer. (*See* Tao Decl. Ex. A, Apotex Inc.'s 11-4-08 Paragraph IV Notice Letter.).[1] To preserve the resources of the parties and the courts, in that notice, Apotex Inc. identified its agent for service of process in Illinois, where Pfizer subsequently sued for alleged infringement of the '995 patent. (*See* Phillips Decl. Ex. A, Dec. 17, 2008 Compl. in *Pfizer Inc. v. Apotex Inc.*,

[1] All references to "Tao Decl." are to the Declaration of Bernice Tao, filed contemporaneously herewith.

No. 1:08-cv-07231 (N.D. Ill.) ("NDIL Compl.")).[2] But apparently unhappy with Illinois, Pfizer decided to shop around for another court, and so also filed this identical action against Apotex Inc., the ANDA-filer, and Apotex Corp., which had nothing to do with the ANDA giving rise to this suit.[3] (*See* D.I. 1, Compl.).

On March 17, 2009, the United States Patent and Trademark Office ("PTO") reissued the '995 patent-in-suit as U.S. Patent No. RE 40,667 E ("the '667 patent"). (D.I. 25 at Ex. B, the '667 patent cover). Issuance of a reissued patent terminates the already existing patent (here, the '995 patent), which ceases to exist. (*See* D.I. 22, Mot. to Dismiss for Lack of Jurisdiction Over the Subject Matter and Failure to State a Claim). Apotex Inc. amended its ANDA to include a paragraph IV certification as to Pfizer's '667 patent as well, and provided Pfizer with the requisite notice of that certification. (Phillips Decl. Ex. S). In response, Pfizer filed an Amended Complaint adding the '667 patent, but maintaining a count for alleged infringement of the now-dead '995 patent. (*See* D.I. 25).

The problem for Pfizer, however, is that Apotex Inc. has no connection to, or presence in, Delaware, much less the "systematic and continuous" contacts required for general jurisdiction. Nor does this litigation arise out of anything that occurred in, or is otherwise connected with, Delaware, as it must for specific jurisdiction. The bottom line is that this Court lacks personal jurisdiction over Apotex Inc., the ANDA-filer and the only party that matters. Dismissal is therefore required and will permit this dispute to proceed where it belongs: in Illinois, where jurisdiction is proper, and where related litigation is pending, including an

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[2] All references to "Phillips Decl." are to the Declaration of John C. Phillips, Jr., Esq., filed contemporaneously herewith.

[3] Apotex Corp. and Apotex Inc. have also separately filed a motion to transfer this litigation to Illinois, where jurisdiction and venue are proper, and where an identical action is pending.

identical action and complaint filed against Apotex Inc. And without Apotex Inc., Apotex Corp. must be dismissed as well for lack of an indispensible party.

II. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS.

Pfizer filed this action on December 17, 2008, together with an identical action in Illinois. (D.I. 1, Compl.; Phillips Decl. Ex. A, NDIL Compl.). On February 12, 2009, by stipulation, Apotex Inc. filed a timely motion to dismiss for lack of personal jurisdiction. (D.I. 9). That same day, Apotex Inc. and Apotex Corp. filed a motion to transfer the case to Illinois. (D.I. 11). Pursuant to a stipulated extension, Pfizer responded to both motions on March 16, 2009. (D.I. 18, 20). On March 17, 2009, Apotex Inc. and Apotex Corp. filed their motion to dismiss for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted. (D.I. 22). On March 23, 2009, Pfizer filed its First Amended Complaint, which added a count for alleged infringement of the '667 patent, as well as a number of jurisdictional allegations. (D.I. 25, First Am. Compl. ¶¶ 28, 34-40, 42, 44-45, 51-56). Pursuant to a stipulated extension, Apotex Inc. and Apotex Corp. now bring this timely motion to dismiss the First Amended Complaint. (D.I. 27).

III. SUMMARY OF ARGUMENTS.

This Court lacks personal Jurisdiction over Apotex Inc. because Apotex Inc. has insufficient contacts with Delaware to satisfy the state's long-arm statute or the requirements of due process. Apotex Inc. is a Canadian corporation with its headquarters in Canada. Apotex Inc. does not maintain any offices in Delaware, nor does it have any property or employees here. In addition, Apotex Inc. directly sells no products in Delaware. Moreover, Apotex Inc. has taken no actions in Delaware giving rise to this action. Personal jurisdiction is therefore lacking. Because personal jurisdiction is lacking over Apotex Inc., which is the only party that matters

and that confers subject matter jurisdiction on this Court, Apotex Corp. must be dismissed as well for lack of an indispensable party.

IV. STATEMENT OF FACTS.

This action arises under the "Hatch-Waxman Amendments," which amended the patent and drug laws "to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991).[4] To achieve that goal, Hatch-Waxman created the ANDA procedure and "a mechanism to facilitate the adjudication of claims of infringement of patents relating to the innovator's drugs" *before* the generic drug has been marketed. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003). For the Court's convenience, we briefly outline the pertinent statutory and factual background.

A. Statutory and Regulatory Framework.

In order to obtain FDA approval to sell a drug that has not been previously approved, like Lipitor® (atorvastatin), a company generally must file a new drug application ("NDA") with complete studies relating to safety and efficacy. *See* 21 U.S.C. § 355(b)(1). An NDA applicant must also file with FDA the number and expiration date of any patent that "claims the drug for which the applicant submitted the application . . . ." 21 U.S.C. §§ 355(b)(1), (c)(2). FDA publishes this information in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

A generic drug company may file an ANDA, just as Apotex Inc. has done here, for FDA approval to market a generic version of a previously-approved NDA drug by

[4] Hatch-Waxman is formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271).

substituting "bioequivalence data for the extensive animal and human studies of safety and effectiveness that must accompany a full new drug application." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). An ANDA applicant generally must also file one of four "certifications" for each listed patent in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii). With certain exceptions not applicable here, an ANDA applicant seeking approval to market a generic drug before expiration of the listed patent must submit a "paragraph IV certification" stating that the listed patent is invalid and/or will not be infringed by the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA applicant must then notify the patentee and NDA-holder of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B). If the patentee files suit within 45 days of receiving notice from the ANDA-filer, FDA approval automatically is stayed—regardless of the suit's merit or lack thereof—until the earlier of 30 months or a judicial determination that the patent is invalid and/or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii); *Eli Lilly*, 496 U.S. at 677-78. The patent owner, like Pfizer here, therefore has every incentive to delay resolution of the action, and in turn, the approval of the competing generic drug for as long as possible.[5]

The submission of an ANDA with a paragraph IV certification constitutes a "technical" or "highly artificial" act of infringement that creates the necessary subject matter jurisdiction for a district court to resolve any disputes regarding infringement or validity *before*

[5] In exchange for this powerful 30-month approval stay, Congress imposed an express statutory duty on all parties to "reasonably cooperate in expediting the action" and empowered the courts, *inter alia*, to shorten the 30-month stay if the brand company breaches this duty. 21 U.S.C. § 355(c)(3)(C); *see also Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 40 (D.D.C. 2000) (explaining that the Hatch-Waxman drafters expected litigation to be concluded during this time). "Obviously, this process is designed to allow for the court to resolve any claim of infringement the original patent owner may have against the ANDA applicant as quickly as possible, and, indeed, the statute requires that, in these actions, 'each of the parties shall reasonably cooperate in expediting the action.'" *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 487 (E.D. Va. 2005) (quoting 21 U.S.C. § 355(c)(3)(C)).

the generic drug is actually sold. *See* 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit an application under [21 U.S.C. § 355(j)] . . . if the purpose . . . is to obtain approval . . . before the expiration of such patent."); *Eli Lilly*, 496 U.S. at 678 (holding that 35 U.S.C. § 271(e)(2)(A) created "a highly artificial act of infringement that consists of submitting an ANDA" with a paragraph IV certification). The "very limited and technical purpose" of this "highly artificial act" is "to permit patent holders to bring suit against generic companies despite the fact that generic companies have not yet infringed the patents at issue." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1349, 1351 (Fed. Cir. 2004). In other words, filing an ANDA does not constitute actual or direct infringement, but instead is "an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." *Warner-Lambert*, 316 F.3d at 1365.

B. Factual Background.

1. Apotex Inc.

Apotex Inc.—the only proper defendant in this matter—is a Canadian corporation with its principal and only place of business in Toronto, Ontario, Canada. (Tao Decl. ¶ 4). Apotex Inc. researches, develops and manufactures quality generic medicines. (*Id.* ¶ 6). All of Apotex Inc.'s facilities or offices, manufacturing or otherwise, are located solely in Canada. (*Id.*) None are located in Delaware. (*Id.*) Nor is Apotex Inc. registered or licensed to do business, or otherwise sell drugs in, Delaware. (*Id.* ¶ 7). Apotex Inc., moreover, does not maintain offices, facilities, local telephone listings, or bank accounts in Delaware; does not own or lease any real property or employ any persons in Delaware; and does not solicit any business in Delaware. (*Id.* ¶¶ 8-10). Nor has Apotex Inc. directly sold any products in the state of Delaware. (*Id.* ¶ 12).

2. Apotex Inc.'s Atorvastatin ANDA.

At issue in this case is the prescription drug atorvastatin, which Pfizer markets under the brand-name Lipitor®. (*See* D.I. 1, Compl. ¶ 9). Apotex Inc. has prepared and filed with FDA, in Maryland, an ANDA for a generic version of atorvastatin tablets 10 mg, 20 mg, 40 mg and 80 mg. (Tao Decl. ¶¶ 15, 19). The generic products that are the subject of Apotex Inc.'s ANDA are not yet approved by FDA, and have never been commercially manufactured, used, marketed, sold, or offered for sale in, or imported into, the United States. (*Id.* ¶ 16). If and when that product is approved by FDA, it will not be directly sold by Apotex Inc. in the United States or Delaware. (*Id.*) Apotex Inc. conducted all of the research, development and manufacturing for the ANDA, and prepared the ANDA, solely in Canada, not Delaware. (*Id.* ¶¶ 17-18).

Apotex Inc.'s ANDA contains a paragraph IV certification for the '995 patent and U.S. Patent Nos. 5,686,104 ("the '104 patent"), 5,969,156 ("the '156 patent") and 6,126,971 ("the '971 patent"), which are all listed in the Orange Book for Lipitor®. (Tao Decl. ¶ 21; *see also* Phillips Decl. Exs. F-K, the '995, '104, '156, and '971 patents and assignment information for the '995 and '156 patents). Apotex Inc. provided Pfizer with the requisite notice of its paragraph IV ANDA filing through a letter from its outside counsel in Illinois. (Tao Decl. ¶¶ 22-23 and Tao Decl. Ex. A, Notice Letter). The letter was sent to the NDA holder and its agent, Pfizer and Pfizer Ireland, in their offices in New York, and to the patent owner, Warner-Lambert, in it's offices in New Jersey and Michigan. (Tao Decl. Ex. A, Notice Letter). As a courtesy, Apotex Inc. also sent a copy of the letter to Pfizer's outside litigation counsel who happens to have their offices in Delaware. (*Id.*) In that notice letter, to conserve the resources of the parties and the courts, Apotex Inc. identified and designated an agent for service of process in Illinois, where, as discussed below, an identical action on the very same patent is already pending. (Tao Decl. ¶ 24 and Tao Decl. Ex. A, Notice Letter at 5).

Upon issuance of the '667 patent, Apotex Inc. amended its ANDA to include a paragraph IV certification to that patent as well. As required by statute and regulation, and as before, Apotex Inc. also sent a second round of notice letters to the NDA holders and patent owners in New York, New Jersey, Michigan and Dublin, Ireland. (Phillips Decl. Ex. S, Second Notice Letter). As with the earlier certification, Apotex Inc. also sent a letter to Pfizer's outside counsel in Delaware, *but only as a courtesy.* These letters also identified and designated an agent for service of process in Illinois. As set forth below, Pfizer, too, has consented to jurisdiction in Illinois by filing an identical action against Apotex Inc. there.

3. Identical Action in Illinois.

Notably, Pfizer has already asserted the '995 patent-in-suit against Apotex Inc. in an identical action filed in Illinois. (*See* Phillips Decl. Ex. A, NDIL Compl.). As noted, Apotex Inc. identified an agent for service of process in Illinois, and has consented to jurisdiction there. (*See* Tao Decl. ¶ 24 and Tao Decl. Ex. A, Notice Letter at 5). In fact, Apotex Inc. has already answered the complaint in Illinois, and also asserted declaratory judgment counterclaims against Pfizer there.

V. ARGUMENT.

On a Rule 12(b)(2) motion to dismiss for lack of personal jurisdiction, the plaintiff, here Pfizer, alone bears the burden of proving that jurisdiction exists. *See Commissariat A L'Energie Atomique v. Chi Mei Optoelectronics Corp.*, 395 F.3d 1315, 1319 (Fed. Cir. 2005); *Provident Nat'l Bank v. Ca. Fed. Sav. & Loan Ass'n*, 819 F.2d 434, 437 (3d Cir. 1987); *Merck & Co., Inc. v. Barr Labs., Inc.*, 179 F. Supp. 2d 368, 371 (D. Del. 2002). Where, as here, Pfizer has elected to sue multiple defendants, Pfizer must meet its burden of establishing personal jurisdiction as to each defendant individually, and may not treat the defendants collectively. *See Eli Lilly & Co. v. Sicor Pharms., Inc.*, No. 06-238-SEB-JMS, 2007

WL 1245882, at *5 (S.D. Ind. Apr. 27, 2007) (citing *Rush v. Savchuk*, 44 U.S. 320, 331-32 (1980)). To satisfy its burden, Pfizer may not rest on conclusory assertions in its pleadings, but rather "must sustain its burden of proof in establishing jurisdictional facts through sworn affidavits or other competent evidence." *Time Share Vacation Club v. Atl. Resorts, Ltd.*, 735 F.2d 61, 66 n.9 (3d Cir. 1984).

When the question before the court in a patent case is the exercise of personal jurisdiction over an out-of-state accused infringer, Federal Circuit law controls. *See Akro Corp. v. Luker*, 45 F.3d 1541, 1543 (Fed. Cir. 1995). A court can exercise personal jurisdiction over an out-of-state defendant if the forum state's long-arm statute, in this case Delaware, permits jurisdiction, and if the exercise of such jurisdiction in the particular case would not violate federal due process as delineated in *Int'l Shoe Co. v. Washington*, 326 U.S. 310 (1945). The Delaware Supreme Court has construed Delaware's long-arm statute, 10 Del. C. § 3104(c), broadly, to confer jurisdiction to the fullest extent allowed under the due process clause. *See Kloth v. S. Christian Univ.*, 494 F. Supp. 2d 273, 277 (D. Del. 2007) (citing *LaNuova D & B S.p.A. v. Bowe Co. Inc.*, 513 A.2d 764, 768 (Del. 1986)). However, Delaware's long-arm statute has not been determined to be coextensive with federal due process and therefore the Court must determine whether the exercise of personal jurisdiction is compatible with both the Delaware long-arm statute and a defendant's constitutional due process rights. *Id.* at 277-78.

Due process requires that a plaintiff establish that the defendant has "minimum contacts" with the forum. *See Deprenyl Animal Health, Inc. v. Univ. of Toronto Innovations Found.*, 297 F.3d 1343, 1350 (Fed. Cir. 2002). To satisfy this burden, Pfizer must establish specific jurisdiction, or general jurisdiction. *See Merck*, 179 F. Supp. 2d at 371. "Specific jurisdiction arises when the particular cause of action arose from the defendant's activities within

the forum state; general jurisdiction arises when the defendant has continuous and systematic contacts with the state, irrespective of whether the defendant's connections are related to the particular cause of action." *Id.* The courts, moreover, have determined that the so-called "stream of commerce" theory of jurisdiction is merely another form of specific jurisdiction. *See Power Integrations, Inc. v. BCD Semiconductor Corp.*, 547 F. Supp. 2d 365, 371 (D. Del. 2008). Pfizer does not, and indeed cannot, come close to meeting its jurisdictional burdens here. The Court therefore should dismiss the case against Apotex Inc. and allow the dispute to proceed in Illinois where identical litigation is pending.

Moreover, to prevent unnecessary delays and expense, the Court should also reject any request for jurisdictional discovery by Pfizer. Indeed, a court is within its discretion to deny jurisdictional discovery where, as here, Pfizer's assertions regarding personal jurisdiction are clearly frivolous. *See Mass. School of Law at Andover v. Am. Bar Ass'n*, 107 F.3d 1026, 1042 (3d Cir. 1997) (affirming district court's refusal to allow jurisdictional discovery). "As such, a court may deny a request for jurisdictional discovery when the plaintiff fails to establish a prima facie showing of personal jurisdiction." *Knierim v. Siemens Corp.*, No. 06-4935 (SDW), 2008 WL 906244, at *11 (D.N.J. Mar. 31, 2008); *see also Hansen v. Neumueller GmbH*, 163 F.R.D. 471, 475 (D. Del. 1995) ("[T]he memoranda which have been filed in response to defendants' motion contain speculation, but no facts by which jurisdiction can be established . . . ." (quoting *Poe v. Babcock Int'l, PLC*, 662 F. Supp. 4, 7 (M.D. Pa. 1985))).

Here, of course, Pfizer has not even attempted to demonstrate or establish jurisdiction with actual facts, much less with any reasonable particularity. Its original pleading is devoid of facts altogether. Pfizer's First Amended Complaint attempts to cure those deficiencies by adding no less than twelve additional allegations in the "Parties, Jurisdiction and Venue"

section of the amended complaint—all of which are baseless. (D.I. 25, First Am. Compl. ¶¶ 21-22, 28, 34-40, 42, 44-45). The most flagrant, if not absurd, alleges that "[a] generic drug company's need to litigate patents covering FDA-approved branded drug products is the central feature of its business model." Such unfounded allegations are clearly an attempt to fabricate a basis for personal jurisdiction that simply does not exist. As this Court has found in similar cases, "[i]t would be inappropriate for this court to allow [Pfizer] to conduct a fishing expedition in order to construct a basis for jurisdiction." *Hansen*, 163 F.R.D. at 475. So too here.

A. This Court Lacks Personal Jurisdiction Over Apotex Inc. Because Apotex Inc. Does Not Have Any Contacts At All With Delaware, Let Alone The Required "Minimum Contacts."

1. Pfizer Cannot Establish Specific Jurisdiction Over Apotex Inc.

The first issue is whether Pfizer can establish specific jurisdiction. It cannot. For specific jurisdiction, "minimum contacts" requires the plaintiff to show that the defendant "has purposefully directed his activities at residents of the forum and the litigation results from alleged injuries that arise out of or relate to those activities." *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1360 (Fed. Cir. 2001) (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 471-76 (1985)). In order for specific jurisdiction to exist, the Court must find that: (1) the defendant purposefully directed its activities at the residents of the forum; (2) the claim arises out of or is related to those activities; and (3) the assertion of personal jurisdiction is reasonable and fair. *See Hollyanne Corp. v. TFT, Inc.*, 199 F.3d 1304, 1307-08 (Fed. Cir. 1999) (citing *Akro*, 45 F.3d at 1545-46). Here, nothing at all has occurred in Delaware, and certainly nothing giving rise to this litigation.

First, as Pfizer concedes, Apotex Inc. has not made, used, sold, offered for sale or otherwise commercialized the generic atorvastatin tablets in Delaware that are the subject of Apotex Inc.'s ANDA. (Tao Decl. ¶ 16). Indeed, that product is not even approved by FDA, and

thus could not, as a matter of law, be sold or marketed in Delaware, or anywhere else for that matter. (*Id.*) Even once it is approved, the product will not be directly sold by Apotex Inc. in Delaware. (*Id.*)

Second, Apotex Inc. did not prepare its atorvastatin ANDA, or develop or compile any of the information necessary for that ANDA, in Delaware. (Tao Decl. ¶¶ 17-18, 25). Rather, Apotex Inc. conducted all of the research, development and manufacturing of the generic atorvastatin products that are the subject of its ANDA solely in Canada. (*Id.* ¶¶ 17, 25). Apotex Inc., moreover, prepared and filed the ANDA from Canada, and submitted it directly to FDA's Office of Generic Drugs in Maryland, not Delaware. (*Id.* ¶¶ 18-19, 25).

Third, notice of Apotex Inc.'s Paragraph IV ANDA was provided to the NDA-holder and patent owner in New York, New Jersey and Michigan by Apotex Inc.'s outside counsel in Illinois. (Tao Decl. ¶¶ 22-23). Apotex Inc.'s second notice letter was also sent to the same jurisdictions, as well as Dublin, Ireland. Moreover, that notice designated an agent for service of process in Illinois, where Pfizer already filed an identical suit, not Delaware. (*Id.* ¶ 24). To the extent Pfizer claims that sending a courtesy copy of the notice letter to its outside counsel constitutes some sort of tort committed on Pfizer in Delaware, Pfizer is dead wrong. The statue requires that notice be provided to the NDA-holder and patent owner. Pfizer's counsel is neither. More importantly, the alleged tort (or act of patent infringement), if any, occurred when Apotex Inc. filed its Paragraph IV ANDA, not when Apotex Inc. sent its notice letters. *Eli Lilly*, 496 U.S. at 678 ("act of infringement that consists of submitting an ANDA"). Pfizer's suggestion that this action arises out of a courtesy copy of a letter sent to its outside counsel is therefore baseless, and certainly not a basis for specific jurisdiction.

In sum, this entire action, and indeed the only basis for the Court's subject matter jurisdiction, arises solely out of the submission of Apotex Inc.'s Paragraph IV ANDA. But nothing, repeat nothing, concerning that ANDA, or anything else giving rise to this action, occurred anywhere near Delaware. Pfizer, therefore, cannot establish specific jurisdiction as a matter of law. *See Hockerson-Halberstadt, Inc. v. Propet USA, Inc.*, 62 Fed. App'x 322, 337 (Fed. Cir. 2003) (finding that there could not be specific jurisdiction where no sales of the allegedly infringing product were made in the forum state); *Mylan Pharms, Inc. v. Kremers Urban Dev. Co.*, No. 02-1628-GMS, 2003 WL 1843858, at *3-4 (D. Del. Apr. 7, 2003) (same).

2. Pfizer Cannot Establish General Jurisdiction Over Apotex Inc.

Where, as here, the cause of action admittedly does not arise out of the defendant's contacts with the forum, the plaintiff must establish general jurisdiction. This requires a substantial showing of continuous and systematic contacts with the forum. *See LSI Indus. Inc. v. Hubbell Lighting, Inc.*, 232 F.3d 1369, 1375 (Fed. Cir. 2000) ("General jurisdiction arises when a defendant maintains 'continuous and systematic' contacts with the forum state even when the cause of action has no relation to those contacts.") (*citing Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414-16 (1984)). "The constitutional requirement for general jurisdiction is considerably more stringent than that required for specific jurisdiction." *Eli Lilly & Co. v. Mayne Pharma USA Inc.*, 504 F. Supp. 2d 387, 393 (S.D. Ind. 2007) (internal quotations and citations omitted). "The contacts required for general jurisdiction must be so extensive to be tantamount to defendant being constructively present in the state to such a degree that it would be fundamentally fair to require it to answer in [a] . . . court [of that state] in any litigation arising out of any transaction or occurrence taking place anywhere in the world." *Id.* (internal citations and quotations omitted).

Neither the Federal Circuit nor the Supreme Court has established a specific test to determine whether general jurisdiction exists. *See LSI Indus.*, 232 F.3d at 1375. Instead, a court must look at the facts of each case to determine whether a defendant's activities within a state are "continuous and systematic." *Id.; Hockerson-Halberstadt*, 62 Fed. App'x at 337. These contacts "must be so substantial and of such a nature as to justify suit against the defendant on causes of action arising from dealings entirely different from those activities." *Hockerson-Halberstadt*, 62 Fed. App'x at 337 (citing *Int'l Shoe*, 326 U.S. at 318). Here, Apotex Inc.'s contacts with Delaware are virtually non-existent, much less "continuous and systematic" as required for the exercise of general jurisdiction.

The general jurisdiction provisions of the Delaware long-arm statute state in relevant part:

> (c) As to a cause of action brought by any person arising from any of the acts enumerated in this section, a court may exercise personal jurisdiction over any nonresident, or a personal representative, who in person or through an agent:
>
> . . . .
>
> (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State.

10 Del. C. § 3104(c)(4). The relevant inquiry for purposes of this motion is whether Apotex Inc. regularly does or solicits business or engages in any persistent conduct in the State, or derives substantial revenue from services or things used or consumed in Delaware. *Id.* Apotex Inc. has no such contacts.

First, Apotex Inc. does not reside in, or otherwise maintain any presence of any kind, in Delaware. (Tao Decl. ¶¶ 4-12). Rather, Apotex Inc. is a Canadian corporation with its sole place of business in Canada. (*Id.* ¶¶ 4-5).

Second, Apotex Inc. does not maintain offices, facilities, local telephone listings, or bank accounts in Delaware, own or lease any real property in Delaware, have any employees in Delaware, or solicit any business in Delaware. (Tao Decl. ¶¶ 8-10). All of Apotex Inc.'s facilities, offices, real estate and employees are located solely in Canada. (*Id.* ¶ 6). Nor does Apotex Inc. have any subsidiaries located in Delaware. (*Id.* ¶ 11).

Third, Apotex Inc. is not registered or licensed to do any type of business in Delaware. (Tao Decl. ¶ 7). Apotex Inc. does all of its research, development and manufacturing in Canada. (*Id.* ¶ 6). Apotex Inc. has never directly sold any of its pharmaceutical products in Delaware. (*Id.* ¶ 12).

In sum, Apotex Inc.'s contacts, to the extent they have any, are not nearly enough to establish general jurisdiction. Indeed, both the Federal Circuit and the Supreme Court have found jurisdiction lacking for defendants with far greater contacts with the forum than Apotex Inc. has here. *See, e.g.*, *Helicopteros*, 466 U.S. at 418-19 (finding no general jurisdiction where defendants received money from bank accounts located in, held meetings in, sent employees to train in, and bought goods from the forum state, but did not maintain an office, sell goods, own property, maintain records or solicit business there); *Hollyanne*, 199 F.3d at 1305 (affirming district court finding of no general jurisdiction where defendant maintained a sales representative and made a presentation in the forum state, but was not qualified to do business, maintained no employees, bank accounts, offices or real estate interests in the state).

Likewise, in *Zeneca Ltd. v. Mylan Pharms., Inc.*, No. 96-1736, 1996 WL 925640 (D. Md. Jan. 6, 1996), the generic ANDA applicant maintained a sales representative to call directly on customers in Maryland, and also had contacts with a regulatory consultant in the state, though it did not manufacture goods in, maintain an office in, rent property in or target

its promotional activities toward the state. The Court held that such activities did not constitute "general and systematic" contacts with Maryland to satisfy general jurisdiction. *See id.* at *6. So, too, did the court in *Merck*, where the generic ANDA applicant was a foreign corporation with no employees, telephone listings, bank accounts or real estate in Delaware. The court held that such contacts did not amount to regularly doing or soliciting business in Delaware, and therefore were insufficient to establish general jurisdiction. *Merck,* 179 F. Supp. 2d at 374. And in *Glaxo Inc. v. Genpharm Pharms.,* 796 F. Supp. 872, 875-76 (E.D.N.C. 1992), the court concluded that it lacked personal jurisdiction over a Canadian defendant who filed an ANDA where the defendant did not regularly transact or solicit business in North Carolina, was not licensed to do business there, had never manufactured, sold, marketed or distributed anything in North Carolina, never leased or owned real property there, and never had a North Carolina bank account, mailing address or telephone number. *Genpharm,* 796 F. Supp. at 877.[6]

Recently, this Court considered a motion to dismiss for lack of personal jurisdiction in another ANDA case with almost identical facts. In that case, two related Defendants asked the Court to dismiss the complaint because, just as here, neither movant had any contact with Delaware. *See,* Report and Recommendation at 1, *Forest Labs. Inc. v. Cobalt Labs., Inc.*, No. 08-21-GMS-LPS (D. Del. Mar. 9, 2009) (attached as Exhibit T to the Phillips Decl.). The Court acknowledged, just like Apotex Inc. here, that the movants do not have "any offices, facilities, employees, telephone listings, bank accounts, or property in Delaware; neither are registered to do business or sell pharmaceuticals here; nor do they advertise, derive

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[6] *See also Glaxo Wellcome Inc. v. Mylan Pharms., Inc.*, No. 96-3477, 1997 U.S. Dist. LEXIS 23930, at *6-7 (D. Md. Mar. 31, 1997) (granting defendant ANDA filer's motion to dismiss for lack of personal jurisdiction because defendant's contacts were "limited at best"); *J-L Chieftan, Inc. v. Western Skyways, Inc.*, 351 F. Supp. 2d 587, 594-97 (E.D. Tex. 2004) (finding no general personal jurisdiction and granting motion to dismiss due to insufficient contacts with Texas); *Helicopteros*, 466 U.S. at 418 (same); *L.H. Carbide Corp. v. Piece Maker Co.*, 852 F. Supp.

substantial revenues or initiate litigation here." *Id.* at 14. The only presence the two movants had in the state was a wholly-owned subsidiary of the first movant whose sole purpose was to incorporate the second movant. *Id. at 3.* Thus, the Court characterized the intervening company as "essentially a shell corporation." *Id.* Plaintiffs nonetheless argued that the movants' contacts with Delaware, which are even more substantial than here, included purchase of materials used in the generic products from Delaware companies, use of a Delaware corporation for "analytic services," the existence of distribution agreements with Delaware companies, clinical trials preformed in Delaware which were submitted with the Defendants' ANDA, sales representatives' visit to Delaware, and the existence of Service Agreements which are governed by Delaware law. *See id.* at 6-10. Even in view of the litany of connections with Delaware Plaintiffs attempted to assert, Magistrate Judge Stark concluded that, "[i]n sum, the record does not demonstrate continuous and systematic contacts between [the movants] and Delaware. Plaintiffs have failed to meet their burden to establish general jurisdiction." *Id.* at 16. The same is true here.

3. Personal Jurisdiction Cannot Be Established Based On Prior Litigation In The Forum.

To the extent Pfizer argues that Apotex Inc.'s consent to personal jurisdiction in other cases in this district subjects it to personal jurisdiction in this case, Pfizer is mistaken, again. Not including the present suit, Apotex Inc. has been a named defendant in at least eleven ANDA suits in Delaware. Apotex Inc. challenged jurisdiction in one suit, but the motion was denied without prejudice and without an adjudication on the merits. *See AstraZeneca Pharms. LP, et al. v. Apotex Inc., et al.*, No. 07-809 (D. Del. 2007). In another suit, the case was dismissed before an answer was filed. *See Purdue Pharma. L.P., et al. v. Apotex Inc., et al.*, No.

1425, 1436 (N.D. Ind. 1994) (same).

07-549 (D. Del. 2007). In most of the remaining suits (9), Apotex Inc. either did not contest, or otherwise submitted to, the jurisdiction of the court, *solely for purposes of that particular action*—which should not constitute an admission of general jurisdiction for all purposes. *See Sanofi-Aventis, et al. v. Apotex Inc., et al.*, No. 07-792 (D. Del. 2007; *Senju Pharm. Co., Ltd., et al. v. Apotex Inc., et al.*, No. 07-779 (D. Del. 2007); *Allergan, Inc. v. Apotex Inc., et al.*, No. 07-278 (D. Del. 2007); *MedPointe Healthcare Inc., v. Apotex Inc., et al.*, No. 07-204 (D. Del. 2007); *MedPointe Healthcare Inc. v. Apotex Inc., et al.*, No. 06-164 (D. Del. 2006); *Boehringer Ingelheim Pharms., Inc. v. Apotex Inc., et al.*, No. 08-65 (D. Del. 2008); *Merck & Co., Inc. v. Apotex Inc.*, No. 06-230 (D. Del. 2006); *Sanofi-Aventis et al. v. Apotex Inc., et al.*, No. 08-347 (D. Del. 2008); *Aventis Pharma S.A., et al. v. Apotex Inc., et al.*, No. 08-496 (D. Del. 2008). Apotex Inc. also filed a declaratory judgment action in Delaware, which was dismissed for lack of subject matter jurisdiction. *See Apotex Inc., et al. v. Pfizer Inc., et al.*, No. 03-990 (D. Del. 2003). But in none of the cases was there ever a finding that Apotex Inc. is subject to general jurisdiction in Delaware.

Moreover, Pfizer cannot establish personal jurisdiction based on prior litigation where Apotex Inc. has consented to personal jurisdiction *solely for those particular litigations*. *See, e.g., Wallace v. Int'l Lifestyles, Inc.*, No. 06-1468, 2008 WL 623811, at *5 (E.D. Pa. Mar. 6, 2008) (finding prior litigation does not necessarily confer personal jurisdiction in Florida such that personal jurisdiction cannot be challenged in Florida); *Abbott Labs. v. Mylan Pharms., Inc.*, No. 05-6561, 2006 WL 850916, at *6 (N.D. Ill. Mar. 28, 2006) ("prior litigation within the [forum state] does not support a finding of general jurisdiction."); *Rosenblat v. Sandia Corp.*, No. 04-3289, 2005 WL 1126879, at *2 (N.D. Ill. 2005) ("the fact that [Defendants] appeared as Defendants in another action in the [forum state] does not mean that they waived all personal

jurisdiction requirements for future actions.") (citing *Mallinckrodt Med. Inc. v. Sonus Pharms., Inc.*, 989 F. Supp. 265, 271 (D.C. Cir. 1998) ("It would be ludicrous to suggest that [Defendants] consented to the jurisdiction of the Court for all time, with respect o all potential competitors, and for all purposes, simply because they once chose to sue the FDA here.")); *United States v. Subklew*, No. 00-3518, 2001 WL 896473 (S.D. Fla. June 5, 2001) (finding no personal jurisdiction despite the fact that defendant had defended an action in the same forum). Any holding to the contrary would turn the jurisdictional analysis on its head by finding jurisdiction, *not* where the defendant had purposefully availed itself of the forum state, but rather where brand companies chose to repeatedly sue the defendant.

The bottom line is that Apotex Inc. has far fewer contacts with Delaware than any of the previous cases, where jurisdiction was found lacking. In these circumstances, Pfizer cannot establish general jurisdiction either.

4. Pfizer Cannot Establish Jurisdiction Under the So-called "Stream-Of-Commerce" Theory Unless It Establishes Specific Jurisdiction.

To the extent that Pfizer is attempting to establish jurisdiction under the so-called "stream-of-commerce" theory because products manufactured by Apotex Inc. in Canada may end up in Delaware, that, too, is insufficient as a matter of law. In its First Amended Complaint, Pfizer alleges that personal jurisdiction over Apotex Inc. is proper because it sells pharmaceuticals to Apotex USA, a Florida corporation, which then distributes the pharmaceuticals throughout the United States, including Delaware. (*See* D.I. 25, First. Am. Compl. ¶¶ 22-23). This argument, however, is unavailing because the "stream of commerce" theory of personal jurisdiction only applies in cases of specific jurisdiction. *See Power Integrations*, 547 F. Supp. 2d at 371. As explained above, there is no basis for alleging specific jurisdiction because nothing occuring in Delaware is related to, or gave rise to this suit. In

Zeneca, the court rejected the "stream of commerce" theory of personal jurisdiction under similar facts:

> Given . . . Supreme Court and Federal Circuit precedent, it is clear that this Court could only exercise specific or "stream of commerce" jurisdiction over the defendant Mylan if the instant action arose out of Mylan's contacts with Maryland, the forum state. . . . [T]he instant action does not arise out of Mylan's contacts with Maryland. As a result, personal jurisdiction over Mylan cannot be maintained by this Court under the "stream of commerce" theory of specific jurisdiction.

Zeneca, 1996 WL 925640, at *4.

For the same reason, Pfizer's stated basis for asserting personal jurisdiction over Apotex Inc. should be rejected.[7]

B. The Exercise of Personal Jurisdiction Over Apotex Inc. Would Offend Traditional Notions of Fair Play and Substantial Justice.

For all the same reasons, the exercise of jurisdiction over Apotex Inc. would offend traditional notions of fair play and substantial justice. *Genetic Implant Sys., Inc. v. Core-Vent Corp.*, 123 F.3d 1455, 1459 (Fed. Cir. 1997) (quoting *Burger King Corp.*, 471 U.S. at 476). Nothing about this action arose or occurred in Delaware, and Apotex Inc. has no contacts there, much less systematic and continuous ones. As this Court concluded in *Merck* under less compelling facts:

> [T]he Court concludes that the requirements of due process are not satisfied because Barr's business contacts with Delaware and its residents are not continuous and systematic. Barr has not availed itself of Delaware resources in that Barr has no employees, bank

[7] Pfizer also cannot establish jurisdiction, general or specific, over Apotex Inc. based on Apotex Corp.'s presence or activities in Delaware. Apotex Corp. is neither owned nor controlled by Apotex Inc., and is not a subsidiary of Apotex Inc. (Tao Decl. ¶ 28). Rather, Apotex Corp. is a separate corporate entity. But even if it weren't, the mere presence of a subsidiary in the forum state does not give rise to the minimum contacts necessary for jurisdiction there. *See Sys. Div., Inc. v. Teknek Elecs., Ltd.*, 253 Fed. App'x. 31, 37 (Fed. Cir. 2007) (jurisdiction over a subsidiary does not automatically provide jurisdiction over a parent)(quoting *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1069 n.17 (9th Cir. 2000)).

> accounts, or real estate in Delaware. Barr does not solicit business, through advertising or otherwise, in Delaware. The total revenue Barr derives from Delaware, approximately $991,000 annually, is less than one percent of Barr's total revenue. Barr has a license to sell pharmaceutical products in Delaware, but is not registered with the Secretary of State to do business in Delaware.

Merck, 179 F. Supp. 2d at 375. In these circumstances, the exercise of jurisdiction would violate the most basic tenets of due process, thus requiring dismissal as a matter of law. *See Carvel v. Griffin*, No. 07-273, 2008 WL 4922432, at *7 (D. Del. Nov. 18, 2008) (Farnan, J.) (granting motion to dismiss for lack of personal jurisdiction due to insufficient contacts with forum state); *Shoemaker v. McConnell*, 556 F. Supp. 2d 351, 355 (D. Del. 2008) (Robinson, J.) (granting motion to dismiss for lack of personal jurisdiction because exercise of the jurisdiction would not comport with due process); *Kee v. Blue Line Distrib., Inc.*, 587 F. Supp. 2d 636, 640 (D. Del. 2008) (Farnan, J.) (granting motion to dismiss for lack of personal jurisdiction due to insufficient "substantial and continuous" contacts with forum).

C. The Action Against Apotex Corp. Should Be Dismissed As Well Because Apotex Inc. Is An Indispensable Party.

Apotex Corp.—which did not prepare or file the ANDA (and is not the ANDA applicant)—is not a proper defendant. If the Court dismisses Apotex Inc. for lack of personal jurisdiction (as it should), the Court should dismiss the action against Apotex Corp. as well, because Apotex Inc., the ANDA-filer, is an indispensable party under Rule 19(b), FED. R. CIV. P., and 35 U.S.C. § 271(e)(2)(A), the only provision conferring subject matter jurisdiction on this Court. Indeed, this entire action, and the Court's subject matter jurisdiction, arises solely out of the submission of a Paragraph IV ANDA by Apotex Inc. *See* 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit an application under [21 U.S.C. § 355(j)] . . . if the purpose . . . is to obtain approval . . . before the expiration of such patent."); *Eli Lilly*, 496 U.S. at 678 (holding that 35 U.S.C. § 271(e)(2)(A) created "a highly artificial act of infringement that

consists of submitting an ANDA" with a paragraph IV certification). Absent the ANDA-filer, here Apotex Inc., there can be no suit at all under 35 U.S.C. § 271(e)(2)(A). It is therefore an understatement to say that Apotex Inc. is an indispensable party to this suit, without which the action against Apotex Corp. must be dismissed as well.

VI. CONCLUSION.

This case does not belong in Delaware, where the only proper party, Apotex Inc., has no contacts and has not otherwise consented to jurisdiction. Rather, the case belongs in Illinois, where Apotex Inc. identified an agent for service of process; has consented to jurisdiction and filed an answer and counterclaims; and where an identical action is pending and proceeding. The Court should therefore dismiss all claims against Apotex Inc. for lack of personal jurisdiction so that this dispute can properly proceed in Illinois. The Court should also dismiss all claims against Apotex Corp. for lack of an indispensable party, and thus dismiss the complaint in its entirety.

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Respectfully submitted,

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